

**REMARKS**

***Status of Claims***

Claims 1-34, 43-45, and 51 stand rejected as allegedly anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,251,407 to Ganne ("Ganne"). Applicants respectfully submit that no new matter has been added by the above amendments.

***Reply to Claim Rejections Under 35 U.S.C. § 102(e)***

Claims 1-34, 43-45, and 51 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Ganne.

To anticipate a claim, a cited reference must teach each and every element of the claim. See M.P.E.P. § 2131, *citing e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). Applicants respectfully assert that the claims as presented are allowable over Ganne, as Ganne fails to disclose a frozen composition, or a composition having the properties of the composition shown in claims 1 and 55. Applicants respectfully submit amended claims to advance the prosecution of this application and further clarify Applicants' arguments over Ganne. Applicants respectfully traverse this rejection because Ganne fails to teach all of the recited claim elements of the amended claims.

In the Office Action, the Examiner asserts that "[t]he claims do not require frozen storage compositions." However, amended claim 1 recites that "the composition is in a solid state." As noted in the Applicants' response dated March 16, 2007 to the Office Action dated October 17, 2006, Ganne does not disclose *any* composition in a solid state. See March 16, 2007 Response to Office Action, page 13. Ganne also does not teach the preparation of a composition in a solid state, or a process of making a solid state composition. Ganne therefore does not disclose storage of a compound in "at least one antigenic medium; and at least one adjuvant, wherein the composition is in a solid

state..." as found in claim 1, as Ganne does not at all disclose freezing compositions for storage. The Office Action also asserts that "[t]he frozen and liquid recitations are latent properties and relate the components of the composition." Office Action, page 3. As shown above, Applicants respectfully assert that "solid state" includes a functional limitation. However, Applicants have amended claim 1 to include the element "wherein the composition is in a solid state" in order to clarify that "solid state" is a functional limitation on claim 1.

Ganne simply does not teach freezing or frozen compositions. Assuming, *arguendo*, that the composition of Ganne was frozen, nothing in Ganne discloses that the resulting solid mass would "comprise one or more phases which are distinct from each other" as disclosed in claim 1. Ganne discloses an emulsion (see col. 3, ll. 45-54), or compositions created by "simple mixing" (see col. 10, ll. 3-6). Ganne does not disclose storage for the composition created, except to state that the composition "must be stable preferably for at least 12 months when it is stored at 4°C." Ganne, col. 3, ll. 59-61. Separation of the antegenic medium and the adjuvant into phases in a solid state is not disclosed in Ganne. As Ganne does not disclose freezing compositions at all, it necessarily cannot disclose separate phases in a solid state. Moreover, Applicants respectfully assert that, from above, Applicants have "show[n] that the prior art composition does not possess the claimed physical characteristics" as requested on page 3 of the Office Action. Applicants respectfully assert that the Office Action fails to make a *prima facie* case of unpatentability based on the arguments above and the Office Action's unsupported assertions.

As shown above, the composition claims 1-34, 43-45 are clearly distinguished from Ganne. In addition, Applicants have also amended claim 55 according to the Examiner's suggestion that the set of claims include a "product by process" claim. The product by process claim appears to address the Examiner's suggestion in the Office Action at pages 4-5.

In view of at least the foregoing, Ganne does not disclose "each and every element as set forth in the claim," and therefore does not anticipate. Applicants

respectfully request withdrawal of the rejection of claim 1, as well as claims 2-34, 43-45, and 51 which depend from independent claim 1, and an indication that the claims are allowable. Applicants also respectfully request entrance of claim 55, which was restricted by the Examiner. Applicants submit that claim 55, as currently amended, is a product by process claim consistent with the Examiner's suggestion, and should be entered for at least that reason.

CONCLUSION

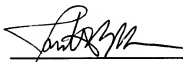
An indication of allowance of all pending claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance. The Commissioner is hereby authorized to charge fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required now or hereafter, or credit any overpayment, to Deposit Account No. 50-0206.

Respectfully submitted,

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